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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,389	10/21/2003	Benjamin Oshlack	6750-362-999	2376

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EXAMINER	
LEA, CHRISTOPHER RAYMOND	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
07/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,389	OSHLACK ET AL.	
	Examiner	Art Unit	
	Christopher R. Lea	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-85,87-96 and 98-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-85,87-96 and 98-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/2208 & 12/9/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner and Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher R. Lea in Art Unit 1619.

This application is a continuation of US patent application 09/777,616 which is a continuation of US patent application 09/360,056 which is a continuation of US patent application 08/833,948 which is a continuation-in-part of International patent application PCT/US95/14745 which is a continuation-in-part of US application 08/334,209.

Receipt of Amendments/Remarks filed on November 3, 2008, is acknowledged. In response to Non-final office action dated June 3, 2008, applicant amended claims 70-74, 87, 88, 93, & 95, canceled claims 86 & 97, and added new claims 98-103. Claims 70-85, 87-96, & 98-103 are pending. Claims 70-85, 87-96, & 98-103 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. All new rejections applied have been necessitated by applicant's amendment to the claims. They constitute the complete set presently being applied to the instant application.

Priority

The examiner wishes to draw to applicant's attention the following problem. Filed concurrently with the application were both an application data sheet (ADS) and an amendment to the specification setting forth applicant's claims to benefit of prior domestic applications. However, the amendment and the ADS are not in agreement, as the amendment sets out a chain of priority and the ADS makes claims of the instant application to each prior application. The examiner believes that the amendment correctly sets out the priority of the application (the claims in the ADS could not be proper as all but the most recent application were not copending with the instant application); however, since both were filed on the same day the ADS is considered the controlling document for bibliographic information as it will appear on published materials. It is strongly suggested by the examiner that applicant file a supplemental ADS to correct the errors on the existing ADS.

Information Disclosure Statement

1. The information disclosure statement(s) (IDS) submitted on s November 3 and December 9, 2008, were filed after the mailing date of the first office action on the merits. Their submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statements have been considered by the examiner.

Response to Arguments – 35 U.S.C. § 112

2. Applicant's arguments, see Remarks pages 10-14, filed November 3, 2008, with respect to the rejection of claims 70-97 under 35 U.S.C. 112 have been fully considered and are persuasive. The enablement and written description rejections of June 3, 2008, have been withdrawn.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 70-81, 87-92, & 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, 18-24, 26-32, 41-50, & 62-66 of U.S. Patent No. 5,958,452 (the '452 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other

because both the instant claims and the claims of the '452 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '452 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '452 patent.

5. Claims 70-75, 77-85, 87, 88, 90-96, & 98-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 8-11, 15-21, 24-31, 33, 37, 39, 41, 46-53, & 57-66 of U.S. Patent No. 5,965,161 (the '161 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '161 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making and using the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '161 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '161 patent. .

6. Claims 70-72, 75, 77-81, 87, 88, 90-92, & 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-25, & 27 of U.S. Patent No. 6,261,599 (the '599 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both

the instant claims and the claims of the '599 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '599 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '599 patent.

7. Claims 70-72, 75, 77-81, 84, 85, 87, 88, 90-92, 95, 96, & 98-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-21, & 24-37 of U.S. Patent No. 6,335,033 (the '033 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '033 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making and using the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '033 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '033 patent.

8. Claims 70-72, 75, 77, 78, 80, 81, 87, 88, 90, 92, & 98-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 7-17, 19, 22, 24-33, & 35-37 of U.S. Patent No. 6,706,281 (the '281 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '281 patent are drawn

to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making and using the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '281 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '281 patent.

9. Claims 70-72, 75, 77-85, 87, 88, 90-96, & 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-24, 27-29, & 32 of U.S. Patent No. 6,743,442 (the '442 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '442 patent are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '442 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '442 patent.

10. Claims 70-72, 75, 77, 78, 81, 100, & 101 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 15-21, 23-27, & 29 of U.S. Patent No. 7,510,727 (the '727 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '727 patent are drawn to an

extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers. The instantly claimed inventions are specific embodiments of the claimed invention of the '727 patent and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '727 patent.

11. Claims 70-72, 75, 77, 78, 80, 81, 87, 88, 90, 92, & 100-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 35, 8-17, 19, 28, 31, & 33 of copending Application No. 12/372,460 (the '460 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the '460 application are drawn to an extruded particulate opioid formulation comprising (a pharmaceutically acceptable salt of) hydromorphone with the hydrophobic materials and fusible carriers as well as methods of making the same. The instantly claimed inventions are specific embodiments of the claimed invention of the '460 application and as such it would have been obvious to the skilled artisan to formulate the instant invention from the claims of the '460 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments – Double Patenting

12. Applicant's arguments filed November 3, 2008, have been fully considered but they are not persuasive. Applicant argues that none of the cited patents teach the

claimed limitations regarding plasma concentration. This is not found persuasive for three reasons. First the limitations to which the applicant refers is prefaced with "when the dosage form contains 8 mg of hydromorphone hydrochloride" which clearly embraces embodiments having more or less than 8 mg; therefore, the limitations concerning plasma concentration only apply to one of several embodiments of the claim. In this respect, they are considered optional. Second, in anticipation of applicant's possible argument that the 8 mg cannot be considered optional (or an amendment to that effect), the examiner asserts that many of the cited patents contain claimed ranges (2 to 64 mg) encompassing a dosage of 8 mg which would make such a limitation obvious. Further, it would have been within the purview of the skilled artisan to determine the therapeutically effective dose and optimize such a dose through routine experimentation. Additionally, 8 mg is a common dosage for hydromorphone, available in both tablets and capsules. Thirdly, the limitations concerning plasma concentration are entirely dependent on the ingredients of the formulation (as applicant has argued in response to the earlier enablement rejection). Since the cited references teach the same ingredients combined in the same ways as those claimed in the instant specification (i.e. the examples), then the claims of the cited references clearly render obvious embodiments that meet those claimed limitations concerning plasma concentration. Items of identical chemical composition cannot have disparate properties. For all these reasons, the obviousness-type double patenting rejections are maintained.

Conclusion

Claims 70-85, 87-96, & 98-105 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 8:00-4:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL
/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616